REMARKS

This Amendment is responsive to the Final Office Action dated August 27, 2007. Applicant has amended claims 1, 21, and 35, and canceled claims 20, 25, 28, and 34. Claims 43-45 were previously withdrawn. Claims 1-4, 9, 10, 12-19, 21-24, 26, 29-33, and 35-42 are pending.

Claim Rejection Under 35 U.S.C. §§ 102(b) and 103(a)

In the final Office Action, claims 1-4, 10, 12-26, and 28-42 were rejected under 35 U.S.C. § 102(b) as being anticipated by Soykan et al. (U.S. Patent No. 6,151,525, "Soykan") or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Soykan in view of Heil, Jr. et al. (U.S. Patent No. 4,819,662, "Heil"). Claims 3, 12-15, 28-31, 36, and 38-42 were rejected under 35 U.S.C. § 103(a) as obvious over Soykan (or Soykan in view of Heil). In addition, claims 9, 24 and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soykan in view of Heil.

Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Soykan, alone or in view of Heil, fails to disclose or suggest each and every feature of the claimed invention, as required by 35 U.S.C. §§ 102(b) and 103(a), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, the applied references fail to disclose or suggest a method that includes eluting genetic material from a polymeric matrix to the stimulation site to cause expression of a protein by the tissue at the stimulation site that increases the conductivity of the tissue at the stimulation site and creates a preferential conduction pathway between the stimulation site and at least one of a bundle of His or a Purkinje fiber of a heart of the patient, as recited by claim 1 as amended.

While Soykan discloses an implantable system that includes a cell repopulation source that includes genetic material to convert fibroblasts into myoblasts,[1] Soykan does not disclose or suggest that the conversion of fibroblasts to myoblasts creates a preferential conduction pathway between a stimulation site and at least one of a bundle of His or a Purkinje fiber of a heart of a

[1] Abstract and col. 4, ll. 54-56.

patient. Soykan is concerned with reversing damage to necrotic heart muscle following myocardial infarction by repopulating the damaged myocardium with undifferentiated contractile cells.[2] Soykan does not specify where the damaged myocardium is located, and, accordingly, Soykan cannot disclose or suggest that that conversion of fibroblasts into myoblasts necessarily creates a preferential conduction pathway to at least one of a bundle of His or a Purkinje fiber of a heart, as required by claim 1

As Applicant's disclosure provides, the bundles of His and Purkinje fibers are made up of cells that are more conductive than the non-specialized myocardial cells that form much of the heart.[3] Typically, pacing pulses delivered to the bundles of His and/or Purkinje fibers provide a more coordinated and hemodynamically effective contraction of ventricles compared to pacing pulses delivered to the non-specialized myocardial cells.[4] Thus, in accordance with claim 1, creating a preferential conduction pathway between a stimulation site and at least one of a bundle of His or a Purkinje fiber of a heart of the patient provides advantages that are not achieved merely by converting fibroblasts to myoblasts. Neither Soykan nor the other applied references contemplates the elution of genetic material to create a preferential conductive pathway to a specific region of the heart, as recited by claim 1.

Soykan does not disclose that the necrotic heart muscle that is being reversed is located near the bundles of His or Purkinje fibers. Thus, even if conversion of fibroblasts to myoblasts increases the conductivity of the cells as proposed by the Office Action, it does not necessarily follow that a preferential conduction pathway is created, or that the pathway is between a stimulation site and at least one of a bundle of His or a Purkinje fiber of a heart. The fact that a certain characteristic may be present in the prior art is not sufficient to establish the inherency of that result or characteristic.[5] A basis in fact and/or technical reasoning must reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.[6] There is no reasonable support for a conclusion that Soykan causes expression of a protein by tissue at a stimulation site that creates conduction pathway that is more preferred that other conduction pathways (i.e., a "preferential" conduction pathway) between the

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[2] Soykan et al. at col. 5, ll. 47-50.
[3] Applicant's originally-filed disclosure at paragraph [0026].
[4] *Id.*
[5] *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ.2d 1955, 1957 (Fed. Cir. 1993); MPEP § 2112.
[6] *Ex parte Levy*, 17 USPQ.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original); MPEP 2112.

stimulation site and at least one of a bundle of His or a Purkinje fiber of a heart of the patient. Soykan only refers generally to "heart muscle" or the "damaged myocardium," and does not disclose or suggest that this "heart muscle" or "damaged myocardium" that is converted to contractile heart muscle[7] provides a conductive pathway to the bundle of His or a Purkinje fiber or provides a conductive pathway that is preferred over other pathways.

In addition, while Soykan discloses the delivery of stimulation to tissue, the only purpose of the stimulation is to provide "the necessary electrical pulses . . . to make the newly formed contractile tissue beat in synchrony with the rest of the heart muscle."[8] Thus, Soykan provides no motivation for improving the characteristics of the interface between tissue and an electrode of an electrical stimulation system via expression of a protein by the tissue that increases the conductivity of the tissue.

Independent claim 21 as amended is directed to a medical lead including a porous electrode and a chamber body that defines a chamber containing a polymeric matrix that absorbs a genetic material and elutes the genetic material via the porous electrode to tissue at the stimulation site, wherein the genetic material causes expression of at least one of a connexin or a gap-junction by the tissue at the stimulation site to increase the conductivity of the tissue at the stimulation site.

With the present Amendment, Applicant has incorporated the limitations of claims 25 and 28 into independent claim 21, and canceled claims 25 and 28. In support of the rejection of claim 25, the Office Action stated that Heil discloses a porous electrode[9], and with respect to the rejection of claim 28, the Office Action stated that it is well-known in the art to provide a genetic material causing expression of connexin.[10] The Office Action referred to Girouard et al. (U.S. Patent Application Publication No. 2004/0158289, "Girouard") to support this assertion of knowledge in the art.[11] However, Girouard, which was filed on November 25, 2003, is not prior art against Applicant, whose application was filed on September 14, 2003. Accordingly, Girouard cannot be used to support an assertion of knowledge in the art. In particular, as the

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[7] Soykan et al. at col. 5, ll. 47-53.
[8] *Id.* at col. 13, ll. 12-14.
[9] Office Action at page 5.
[10] *Id.*
[11] *Id.* at page 7.

MPEP § 2144.03 provides, "[i]t would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known."[12]

Applicant submits that genetic material causing expression of connexin to increase the conductivity of tissue at a stimulation site is not capable of instant and unquestionable demonstration of being well-known. Girouard is not prior art and, therefore, cannot support the official notice of facts asserted to be well-known. Applicant respectfully requests the Examiner present a prior art reference that provides authority for the assertion that is well-known in the art to provide genetic material that causes expression of connexin or a gap-junction to increase the conductivity of tissue at a stimulation site.

The cited prior art fails to disclose or suggest a medical lead including a chamber that contains a polymeric matrix that elutes a genetic material to tissue at a stimulation site to cause expression of at least one of a connexin or a gap-junction, as recited by independent claim 21. For example, Soykan does not disclose delivering a genetic material that causes expression of at least one of a connexin or a gap-junction by tissue. Instead, as described above, Soykan is concerned with repopulating damaged myocardium with undifferentiated contractile cells.[13] In addition, Heil only discusses a matrix that elutes a drug and does not contemplate elution of a genetic material, much less elution of a genetic material that increases the conductivity of tissue at the stimulation site. Heil does not recognize that expression of at least one of connexin or a gap-junction may provide advantages over elution of a drug, such a desired effect that lasts longer and is more localized than that of drug.[14] Based on the lack of disclosure within Soykan and Heil, Soykan in view of Heil cannot render independent claim 21 obvious.

In addition, Applicant notes that there is no indication within either Heil or Soykan that modifying Soykan in view of Heil to include a chamber body that includes a matrix that elutes a genetic material to tissue at a stimulation site via a porous electrode would reasonably be expected to be successful. That is, based on the Heil and Soykan disclosures, there is no indication that elution of a genetic material via a porous electrode that also delivers electrical

[12] MPEP § 2144.03 (emphasis in original).
[13] Soykan et al. at col. 5, ll. 47-50.
[14] Applicant's originally-field disclosure at paragraph [0011].

stimulation to tissue would be successful in causing expression of at least one of a connexin or a gap-junction by the tissue at the stimulation site.

Independent claim 35 as amended recites a method that comprises placing a polymeric matrix into a chamber formed by a chamber body of a medical lead for elution of genetic material to tissue of a patient at a stimulation site, where the genetic material causes expression of at least one of a connexin or a gap-junction by the tissue at the stimulation site to increase the conductivity of the tissue at the stimulation site, and where the matrix elutes the genetic material to the stimulation site via a porous electrode of the medical lead. For the reasons discussed above with respect to independent claim 21, claim 35 is patentable over the applied references.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's independent claims 1, 21, and 35 under 35 U.S.C. §§ 102(b) and 103(a). Claims 2-4, 9, 10, and 12-19 depend from claim 1, claims 22-24, 26, and 29-33 depend from claim 21, and claims 36-42 depend from claim 35. Dependent claims 2-4, 9, 10, 12-19, 22-24, 26, 29-33, and 36-42 are allowable for at least the reasons discussed above with respect to the independent claims. Reconsideration and withdrawal of the rejection of the claims is respectfully requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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